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TPCH CENTER 1600

In re Application of: CEFALI, EUGENIO
Serial No.: 08/962,027
Filing Date: 31 October 1997
Docket Number: 50454-56103USCIP1
Title: INTERMEDIATE RELEASE NICOTINIC ACID COMPOSITIONS
FOR TREATING HYPERLIPIDEMIA HAVING UNIQUE CMAX,
TMAX AND AUC BIOPHARMACEUTICAL CHARACTERISTICS

COMMISSIONER FOR PATENTS

P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

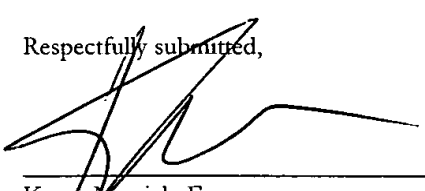
Sir:

Applicants and their attorney are aware of the following publications and information, listed on the attached PTO Form 1449, and in accordance with 37 CFR §1.97(c) hereby submit these publications for the Examiner's consideration. This Statement is being filed after the first Official Action under 37 CFR §1.97(c)(2). Please charge our deposit account number 50-2543 the amount of \$180.00 as specified in 37 CFR § 1.17(p). A full copy of each cited publication is enclosed.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, the Applicant understands the Examiner will make an independent evaluation of the cited publications. No additional costs are believed to be due in connection with the filing of this disclosure. However, please charge any necessary fees to our Deposit Account No. 12-0448. For this purpose we enclose a duplicate copy of this document.

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Respectfully submitted,

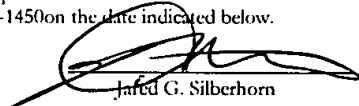

Karen Messick, Esq.
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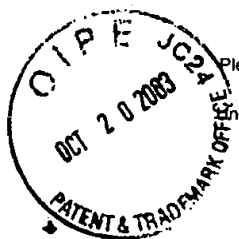
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Date: 10/17/03

CERTIFICATION UNDER 37 C.F.R., §1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Complete if Known		
			Application Number	08/962,027	
			Filing Date	10/31/1997	
			First Named Inventor	Cefali	
			Group Art Unit		
			Examiner Name		
Sheet	1	of	1	Attorney Docket Number	50454-56103USCIP1

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	Dialog File 226: Trademarkscan(r)-US FED: Accession number 73/838497	
	2	McCarthy on Patents, Sec. 19.110	
	3	199 U.S.P.Q. 824 (Endo Laboratories, Inc. v. Fredericks, 08/18/1978)	
	4	KEENAN, et al., A Clinical Trial of Oat Bran and Niacin in the Treatment of Hyperlipidemia", Jour. Fam. Prac., 34:3, 313-317 (1992)	
	5	KNOPP, et al., "Contrasting Effects of Unmodified and Time-Release forms of Niacin on Lipoproteins in Hyperlipidemic Subjects: Clues to Mechanism of Action of Niacin", Metabolism, 34:7, 642-650 (1985)	
	6	Letter to Applicant from U.S. Department of Health and Human Services dated 07/28/1997	

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Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

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